

April 3, 2015

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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Dear Dr. DeSalvo:

The RSNA is pleased to offer comments on the draft document entitled, “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap.”

We have submitted responses to the specific questions included with the request for comments using the form available on the www.healthit.gov website and convey them in the attachment to this letter. Some of our comments were developed in coordination with healthcare organizations we work with through the Integrating the Healthcare Enterprise (IHE) initiative.

We would first like to thank ONC for focusing the attention of the healthcare community on interoperability. We believe we are poised to make tremendous advances in the quality, safety and efficiency of healthcare by taking full advantage of data in the care of each patient and the broader patient population. Currently we fail to do so because the patient’s full record is scattered in inaccessible data silos. This information needs to be made available to care providers, safely and securely, with proper patient control and consent. Effective, standards-based interoperability is the path toward this goal.

In our comments we note that the Roadmap provides relatively little focus on interoperability issues specific to medical imaging. We understand that this may be because it is intended as a high-level overview. We wish to emphasize, however, that adequately addressing the standards needed to enable the secure, convenient exchange of medical images and related information is a critical element in achieving interoperability. Given that observation, we attach as an addendum a document we forwarded to ONC in January 2014 that expresses a vision of the evolving standards related to image exchange. We believe this document is relevant to the national interoperability roadmap because it offers the level of detail on imaging standards needed to achieve interoperability.

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Thank you for the opportunity to share these views. We hope that this discussion and our collective efforts will bring a higher quality of care and better health outcomes to our patients.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Ehman", with a long horizontal flourish extending to the right.

Richard L. Ehman, MD
Chair, RSNA Board of Directors

RSNA Comments to ONC on “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap”

1. General

ONC has identified three critical pathways required to deliver better care and health:

- 1) Requiring standards;
- 2) Motivating the use of those standards through appropriate incentives; and
- 3) Creating a trusted environment for the collecting, sharing and use of electronics health information.

We applaud each of these objectives. Continuous focus and progress on achieving these objectives will lead to success in creating a “learning health system.”

The principle expressed early in the Roadmap to “Build upon Existing Health IT Infrastructure” deserves even more emphasis than it receives through the remainder of the document. IHE has developed an extensive set of standards-based implementation guides (called IHE profiles) that address interoperability issues within and across care settings that have been deployed widely in health IT products and care sites around the world. Many commercial vendors have also put in place technical solutions that provide interoperability features. Some of these, however, are proprietary, limiting the breadth of adoption and emphasizing the need for a strong national policy on standards.

In the near term, much can be accomplished using existing technologies by promoting and incentivizing the adoption of appropriate policies for information sharing. The introduction of new technical solution is likely to require a more measured pace to ensure that they have been carefully validated.

We are pleased with the Roadmap’s emphasis on innovation, but also wish to call out the value of stability in the health IT ecosystem, since billions of dollars will be spent to implement interoperable systems. In the world of consumer technology quick transition from established technologies may be acceptable and the market alone may govern the pace of change. In healthcare, providers invest enormously in training and technology, and this investment should be encouraged and supported. Volatile market forces must be balanced with considerations of patient safety, data security, and societal cost.

The Roadmap encourages innovation partly through an emphasis on “open APIs,” especially those based upon RESTful services and HL7 FHIR. (This approach was also advocated in the

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recently published JASON reports.) We also look forward to the availability of these technologies, but fear that too great an emphasis on them may delay implementation and use of other open APIs being used successfully by HIEs, like the IHE XDS family of profiles, which are based on Web services. These technologies have been widely deployed for only a few years and have supported the goals of secure exchange very well in implementations around the globe.

We recognize that there are use cases where RESTful solutions provide lighter weight and nimble solutions. We should, however, carefully identify where a measured transition is needed in implementation of new technologies. For example, while the draft document cites the architectures of modular consumer applications, none of these platforms has so far been shown to support the granular level of information required in the management of complex health conditions. Hastily adopted solutions may not prove adequate to support healthcare practice. This should not discourage new development, but should caution us about the pace at which these solutions reach maturity. Moreover, the discipline required to provide effective technical solutions does not change fundamentally as technology evolves. Applications based on RESTful services, for example, still require expert health IT support.

We thus also applaud the principle stated as, “Interoperability is More than Technology,” and suggest that it too deserves greater emphasis throughout the report. In order to ensure that technical standards are, as the report recommends, “embedded in a market ecosystem of reasonable and customary practices,” the definition of clear use cases must precede the choice of available technical solutions and governing standards.

Social, economic and political forces have often been more important barriers to interoperability than an absence of technical standards. Interoperability will be achieved rapidly and efficiently when clear business incentives for adopting interoperable systems provided and policy barriers to sharing information are removed.

Market-based strategies that center on purchasers of care and private payers, with the support and leadership of CMS, can incentivize adoption of standards-based interoperability solutions for specific clinical use cases. ONC can help by convening private and public-sector payers to coordinate strategies to promote interoperability. ONC can also play a leadership role in coordinating across federal agencies to inform them about activities to achieve standards-based interoperability across the health IT ecosystem and to encourage their participation.

The Roadmap acknowledges that security and privacy concerns have sometimes been a barrier to achieving interoperability and information sharing. Again, ONC can play a leadership role by clearly articulating the impact of federal health IT policies regarding privacy and security to the health IT community and by coordinating efforts with other agencies to reduce unnecessary obstacles to information access.

Proper, sustained governance of standards remains a pre-requisite for effective interoperability, even with new technologies such as Open APIs. This need for governance has been known for many years by the health IT industry and was recognized in the JASON reports. It has been a motivating principle of IHE over its fifteen years of continuous work. IHE committees conduct annual cycles of development, testing and review of these specifications in 13 domains overseen by numerous stakeholder organizations. The work of IHE also involves ongoing collaboration with other standards development organizations like HL7, DICOM, IEEE, OASIS, IETF, and W3C; trade associations like NEMA-MITA and the EHRA; industry initiatives such as Continua, the Care Connectivity Consortium, Carequality, and the EHR|HIE Interoperability Workgroup; and HIE networks, including the eHealth Exchange.

We believe that ONC can exercise effective leadership by providing high-level governance of the diverse stakeholders in health IT, communicating clear and consistent direction on national priorities such as the learning health system. When appropriate, ONC should act as a convener and an active participant in these groups. ONC has a key role to ensure that standards selection process follows transparent, objective, and neutral processes. Recent examples of successfully joint efforts are the Data Access Framework (DAF) and Healthcare Provider Directory/Federated (HPD/Federated). In both of these cases, the ONC provided convening functions, and provided staff support to the SDO, which has helped to accelerate these important efforts. The ONC should use these two highly successful efforts as a pattern for future collaboration.

Finally, a learning health system must include testing, test tooling and certification as intrinsic parts of planning and implementation. Currently available testing tools are not sufficient to the need. Development of adequate tools should become a national priority in which ONC and other health IT stakeholders invest substantial resources. ONC should convene stakeholders to develop a coordinated national system for testing that eliminates redundant efforts and gaps in testing capabilities and includes a feedback loop to ensure continuous improvement of testing tools as new knowledge is gained.

To reiterate, IHE is very much aligned with the general goals and objectives stated in the Roadmap and ready to collaborate with ONC and other stakeholders to progress toward achieving an effectively interoperable learning health system.

Question: 1.1. Are the actions proposed in the draft interoperability roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?

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We are generally supportive of the actions proposed in the Roadmap, particularly the four foundational “Critical Actions for Near Term Wins.” We offer the following comments on these recommended actions:

1. *Establish a coordinated governance framework and process for nationwide health information interoperability.* The Roadmap should emphasize the role of ONC in convening health IT stakeholder workgroups to outline a general governance and trust framework, establish roles and responsibilities and identify areas of collaboration and harmonization. These workgroups should also be responsible for curating the Roadmap itself, an activity that should be iterative and consensus-based.
2. *Improve technical standards and implementation guidance for sharing and using a common clinical data set.* ONC’s primary role should, again, be to convene stakeholders, including developers and users of health IT data standards and systems, to select appropriate standards for specific use cases and plan the ongoing development and curation of necessary standards. ONC should not develop new standards, but should influence development and selection of standards, mainly through the identification of use cases. Standards development should be performed by standards development organizations with expertise in the relevant domain. ONC has a key role to ensure that standards selection process follows transparent, objective, and neutral processes. Recent examples of successfully joint efforts are the Data Access Framework (DAF) and Healthcare Provider Directory/Federated (HPD/Federated). In both of these cases, the ONC provided convening functions, and provided staff support to the SDO, which help accelerate these important efforts. ONC should use these two highly successful efforts as a pattern for future collaboration. In addition, ONC should recognize that standards will require broad review, piloting, and feedback loops in order to mature sufficiently that they can be used in stable national-scale production deployments.
3. *Advance incentives for sharing health information according to common technical standards, starting with a common clinical data set.* We strongly agree that additional incentives are needed to provide a clear business case for interoperability and information exchange. The ONC should provide incentives for organizations that demonstrate true interoperability, which can be defined as secure and seamless access to patient information across care settings. Market-based strategies that center on purchasers of care and private payers, with the support and leadership of CMS, can incentivize adoption of standards-based interoperability solutions for specific clinical use cases. ONC can help by convening private and public-sector payers to coordinate strategies to promote interoperability. ONC can also play a leadership role in coordinating across federal agencies to inform them about activities to achieve standards-based interoperability across the health IT ecosystem and to encourage their participation. ONC should

provide non-regulatory incentives that align with the objective of lowering the barriers to provider-to-provider and patient-to-provider information sharing.

4. *Clarify privacy and security requirements that enable interoperability.* We strongly agree that clarification of these requirements can help remove concerns underlying privacy and security policies that needlessly hinder sharing of information.

Question 1.2 What, if any, gaps need to be addressed?

A critical gap that requires additional attention are the incentives and barriers to information sharing in healthcare. Care providers currently do not have strong or consistent business incentives for sharing information with patients and other care providers. Furthermore, they confront many obstacles to sharing such information, not only technical issues, but also policy considerations such as patient privacy and security concerns. Through the Meaningful Use program or other levers, ONC should, perhaps in concert with other federal agencies, consider providing specific incentives for provider-to-provider and provider-to-patient information sharing. ONC should also work with the Office of Civil Rights to ensure that privacy and security protections are implemented in ways that do not impede sharing information with patients or authorized care providers.

Another current gap is the identification of priority use cases. Without well-defined use cases, it is impossible to judge the adequacy of a given standard, architecture or solution. For example, the Direct Project might have achieved greater success if it had proceeded from a clearly defined use case. We thus applaud the roadmap's recognition of the value of use cases in Appendix H, and question 2.

We also believe that the Roadmap should identify a more detailed sequence of activities to address interoperability priorities, such as coordinated training and reference implementations. Keeping in mind the natural sequencing of these activities and the associated interdependencies will help the roadmap achieve optimal deployment and adoption.

Finally, we support the principle stated in the Roadmap that healthcare should be "person-centric," and see the need to identify specific policies regarding consent, access, corrections, remote monitoring, person engagement, person control and accountability of their records. PHR use should be incorporated into the national roadmap.

Question 1.3. Is the timing of specific actions appropriate?

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Not in all cases. We believe the Roadmap should reflect the current availability of well-developed and widely adopted standards. ONC should encourage continued rapid deployment of these standards. It should simultaneously outline the process by which new standards are made ready for deployment. Standards must include well-defined use cases, detailed technical specifications and then higher-level implementation guides (such as IHE profiles) that identify policies and deployment architectures for production use. Furthermore, standards and implementation guides must be piloted before they can be effective at the national level. These considerations should be addressed in the ONC roadmap. A key example where a more detailed process and timeline is needed is in the implementation of HL7 FHIR, which is listed in the roadmap for immediate adoption. ONC should instead take into account the full standards maturation process to determine when any new technology is ready for use.

Question 2: Priority Use Cases

RSNA identifies the following three use cases as having the highest priority:

#6. Providers and their support staff should be able to track all orders, including those leaving their own organization and EHR, to completion.

#18. Patients have the ability to access their holistic longitudinal health record when and where needed.

#29 Query-based exchange should support impromptu patient visits in all settings.

Use cases should drive the interoperability Roadmap, and ONC should combine and rationalize them as appropriate. Some priorities on the current list are short-term, while others are medium- and long-term; some are very detailed, while others are broad and general. We recommend that ONC develop a “Top 10” list with a fully detailed explanation of their goals, dependencies and timing.

Question 3.1. The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?

There are currently community-led initiatives with broad representation, strong governance and transparent processes. We believe the ONC should act both as a convener of these organizations

to coordinate their work and as an active participant in this process. RSNA, like many peer organizations, currently participates actively in many SDOs, trade associations and physician groups pursuing various aspects of interoperability.

Question 4. 1. How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?

When payers have clearly incented the use of interoperable standards, this has been an effective driver of change to support information sharing, resulting in reductions in cost and improved care. The ONC should act as a convener to encourage payers to provide financial incentives to healthcare providers sharing healthcare information through standards based interoperability solutions.

Question 5.1. What security aspects of RESTful services need to be addressed in a standardized manner?

This question is difficult to answer without a clear description of the use cases being considered for RESTful services to drive security requirements. If the assumption is made that the selected Use Cases result in requirements that include local autonomy, the ability of the disclosing party to have sufficient information about the context of a request to make an access control decision and detailed audit logging, then the security aspects of RESTful services can be met with the existing IHE profile called Internet User Authorization (IUA) based on the OAuth 2.0 standard. There must be the conveyance of attributes, such as the requesting organization, the purpose of the request, the person making the request, patient consent, etc.

Any policy adopted in this regard should not terminate or replace work that is already widely implemented. Different security solutions will need to coexist, with bridges between different technological platforms (SOAP, REST, etc.).

Question 6.1. Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

Generally, we agree with the observation stated early in the Roadmap that “Electronic health information is not sufficiently structured or standardized and as a result is not fully computable

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when it is accessed or received.” There needs to be an emphasis on remedying this situation, especially prior to depending on robust RESTful solutions that will take advantage of granular information.

Assuming that the foundational use case to be addressed is a “transitions of care summary” use case, one issue that needs to be further specified in proposed common clinical data set, is that certain problems, medications, procedures, and other elements can appear in multiple locations. This makes it much more difficult for systems to “receive, find and use” the data elements effectively. The locations of these elements need to be constrained to meet well-defined use cases.

The C-CDA implementation guide is rapidly improving in this regard, and ONC should encourage further improvements by soliciting clinical input to help create a more constrained (and thus more interoperable) version of C-CDA. ONC should also consider providing SDO staff support for this effort, similar to the successful DAF and HPD/Federated projects.

The same is true, to an even greater degree, if the proposed clinical data set is to be expressed in HL7 FHIR. FHIR is designed as an “80% standard,” meaning that it will require extensions and content profiling for each use case. ONC can play a critical role in the work to profile FHIR for use with the selected priority use cases.

Medical vocabularies and ontologies are maturing but yet widely enough adopted to achieve the goals expressed in the roadmap. Initiating exchange of C-CDA level 1 and 2 documents would be a significant advance in providing clinicians narrative text information. Transitioning to level 3 documents as vocabularies mature would build on an established practice of information exchange to achieve greater levels of automation and data analysis. The Roadmap lists 19 elements in the Common Clinical Data Set, but to achieve a learning health system, we will need to come to consensus on vocabularies containing significantly more elements.

In the near term, exchange of even relatively unstructured narrative documents will serve to significantly improve care. It will provide a transitional step toward data-rich, person-centric health IT environment for clinicians still adjusting to electronic medical records and the absence of the traditional patient chart.

Finally, we would recommend inclusion of medical image and reports in the common clinical data set. The experience of image-focused health information exchange programs in the US and elsewhere, including the RSNA’s NIH-funded Image Share Network, suggests that standards and technologies now in place support secure exchange and access to this vital component of the patient record.

Question 6.2. Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?

The proposed efforts to improve Accurate Individual Data Matching provide a sensible approach to addressing a critical issue in information exchange. Building on the IHE PIX/PDQ and XCPD profiles by defining a detailed set of required demographic information would address the problem of variability in implementations of matching algorithms. We also support the goal of establishing acceptable risk levels for probabilistic matching algorithms and the proposed data gathering and analysis effort to achieve this goal. If modifications to the relevant IHE profiles are required to implement lessons learned and support the improvements envisioned, IHE committees would act expeditiously on any requested changes.

We recommend that ONC convene stakeholders to review and refine the recommended minimal set of standardized attributes for patient matching. For example, the list should be augmented with pediatric demographics to help with that vulnerable population. Other additions might include name history, and, phone number types (work/ mobile/home).

We concur with observations in the Roadmap concerning data quality and completeness issues. A holistic approach, including training and design optimization should be used, taking into account issues such as human workflow motivators that often result in suboptimal use of software systems.

The ONC should also recognize that it takes time to align health systems across organizational boundaries. Existing approaches for patient matching are sufficient to enable secure exchange of health information with appropriate supporting policies and practices. The efficiency of exchange and alignment will improve incrementally as methods are refined and become widely familiar.

Question 7.1. In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)

The best practice, we believe, is to require that systems demonstrate all of the following capabilities:

- 1) Receiving systems can display all information provided in the transmission including discrete data elements, narrative text elements, information provenance, author(s) and more.

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- 2) Receiving systems can incorporate all information provided in the transmission into a data repository both as a single unit of information AND by parsing and storing each individual element of the transmitted data.
- 3) Receiving systems can generate reports of the discrete data showing that the data is useful for analytics. (Many systems today just store the clinical data documents as a single unit making it unavailable for analytics or reporting.)
- 4) Sending systems can store and transmit all discrete data elements and demonstrates production deployment of such capabilities. (Many systems in production today have passed MU2 and MU2 / NIST C-CDA and C32 content tests, but in production many data elements are missing.)
- 5) Sending systems can deploy trigger events to push clinical data to exchange partners automatically. (Many systems today have not deployed the ability to share data even though they have this capability.)
- 6) Clinical systems can respond to automated queries for clinical data. (Many systems have demonstrated the capability to perform this function, but have not deployed it in production.)

We wish to emphasize the frequent gap between the tested capabilities of systems and the capabilities activated in real deployments. For example, many health IT systems have already been tested for their support of IHE profiles to share clinical data. But these capabilities are not configured or “turned on” in many production deployments, resulting in a lost “easy win” for the industry. Again, clear incentives for sharing would encourage purchasers of these systems to take full advantage of their information sharing capabilities.

Question 8. Measurement

1. Does the measurement and evaluation framework cover key areas? What concepts are missing?

Beyond initial measurement of core data sets, ONC should look to measure the exchange of specific data types. Survey data should be employed secondarily as it is subject to a variety of behavioral influences that may skew the results. The import of data elements should receive focus more so than the capability to export, as this is a better indication of true demand for and exchange of data.

2. Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?

ONC should focus on early demonstration of the capability to exchange a core measure set. Subsequently the measurement of providers exchanging real world data should be the primary focus. While measurement of potentially diminished costs and the development of a learning health system are desirable, these goals have many underlying drivers and measuring the role of interoperability in delivering these goals may be difficult.

3. Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g., encounter, patient, provider, organization)?

This should be sequenced. Provider and organization interoperability should be measured first followed by patient and encounter measurement.

4. What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?

In the long term, the roadmap suggests measuring outcomes. While this is certainly the long-term goal of our national health policy, it may be beyond current ONC goals, given limitations in resources. ONC may turn to stakeholders for very specific outcome targets that might lend themselves to health IT interoperability solutions. Surveillance programs and diminution in the spread of target diseases might be useful outcome measures.

5. What measurement gaps should be prioritized and addressed quickly?

The measurement of information retrieval rather than push of information will be a true indicator that the health system is utilizing data arising from external source.

HIPAA breaches should be measured as part of this program. These are indicators where "rushed" interoperability solutions may need to be revisited.

6. What other available data sources at the national level could be leveraged to monitor progress?

Payment data indicating redundant utilization of resources would be a useful indicator. Redundant services should diminish with the achievement of full interoperability.

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7. Are the potential mechanisms for addressing gaps adequate? What are other suggestions?

Patient-connected devices are likely to rapidly escalate in utilization during the timeframe encompassed by the roadmap. ONC should develop a set of metrics to indicate how this information is incorporated into the medical record. The exchange of data from the local device into the longitudinal medical record will be a measure of the progress of the overall system with regard to interoperability.

8. How should data holders share information to support reporting on nationwide progress?

Data holders should be incentivized to provide key impact measures using a specified standards-based mechanism for exchanging this information.

9. What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?

In the near term, existing claims data for redundant services in areas like laboratory and imaging may provide a reasonable measure of the impact of interoperability solutions. In the longer term, it should be the goal to use structured clinical data to perform outcomes analysis and comparative evaluation of population health measures across different health IT regimes.

**Response by the Radiological Society of North America (RSNA) to Comment Question:
What actions are your organization planning to take and willing to commit to that will support interoperability?**

The Radiological Society of North America (RSNA®) is an international society of radiologists, medical physicists and other medical professionals with more than 54,000 members from 136 countries across the globe. RSNA hosts the world's premier radiology forum, drawing approximately 55,000 attendees annually to McCormick Place in Chicago, and publishes two top peer-reviewed journals: Radiology, the highest-impact scientific journal in the field, and RadioGraphics, the only journal dedicated to continuing education in radiology.

RSNA oversees a set of informatics-related projects that support the goals of ONC and the Roadmap. We are a sponsor of the IHE initiative and convene the Radiology committees of that organization. We also convene DICOM Working Group 8, which defines standards for structured reporting in radiology. We publish the RadLex terminology and RadLex Playbook, resources to enable more uniform expression of radiology concepts in diagnostic reports and other information. We have developed a set of more than 200 reporting templates, the RadReport template library, that enable consistent and comprehensive structured reporting of specific radiology procedures. Finally, we are the prime contractor on the NIH-funded Image Share Network, a nationwide, patient-focused image exchange network.

Through its journals, annual meeting and other offerings, RSNA regularly conducts programs to educate radiologists and other clinicians, as well as developers, implementers and users of imaging systems regarding the benefits of health IT interoperability and how to achieve them. This includes regularly publishing education materials, conducting workshops and Webinars, and presenting public demonstrations at its annual meeting and other healthcare meetings around the World. We would be happy to collaborate with ONC to ensure that messages supporting the goals of the Roadmap are communicated to the broader health and health IT community.

RSNA representatives have participated actively in ONC sponsored activities and committees. Drs. David Mendelson and Curtis Langlotz, members of the RSNA Radiology Informatics Committee, have provided testimony and participated in meetings of ONC committees on behalf of IHE. RSNA also regularly participates in the Physicians EHR Coalition (PEHRC), which convenes regularly to coordinate the work of medical organizations to advance the use of health IT.

RSNA looks forward to continued opportunities to participate as a stakeholder in ONC committees and activities, including those outlined in the Roadmap, and to comment on and contribute to the work of ONC in achieving the goals the Roadmap puts forth.

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